COLORADO STATE BOARD OF PHARMACY
February 21, 2013

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, RPh, at approximately 8:55 a.m. on Thursday, February 21, 2013 at 1560 Broadway, Conference Room 1250 C, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Professions and Occupations Policy Number 80-17.

Board members attending were: Jeannine Dickerhofe, RPh; Heather Hawker, JD; Donald Johnson, RPh; Paul Limberis, RPh; Ginny Orndorff, MBA; Armand Potestio, RPh; and Luis Rivera-Lleras, RPh.

Staff members attending were: Wendy Anderson, RPh, Program Director; Chris Gassen, RPh, Chief Inspector; and Jean Rowcliffe, Complaint and Licensing Specialist. Also present were Jo Kaye, Assistant Attorney General, and Jack Wesoky, Senior Assistant Attorney General to advise the Board.

Program Director's Report

Ms. Anderson requested that the Board nominate a voting delegate for the National Association of Boards of Pharmacy Annual Meeting to be held on May 18 through 21, 2013 in St. Louis, Missouri. The Board voted unanimously to delegate Donald Johnson, RPh, as the voting delegate.

Ms. Anderson also requested that the Board nominate an observer to participate with the Accreditation Council for Pharmacy Education evaluation team as it evaluates the Doctor of Pharmacy Program at the Regis University School of Pharmacy on April 2 through 4, 2013. The Board selected Luis Rivera-Lleras, RPh as the Board's observer.

New Business

Compounding

Ms. Anderson reported that while 566 nonresident pharmacy affidavits were mailed pursuant to the Board's December 10, 2012 directive, 86 nonresident pharmacies did not respond. In these affidavits, each pharmacy was to attest that it would only dispense and deliver prescriptions into Colorado pursuant to valid, patient-specific prescription orders. After careful consideration of the available information, the Board voted unanimously to initiate a case against each of the nonresident pharmacies that did not respond.

Ms. Anderson reported that various facilities maintain dual out-of-state wholesaler and nonresident pharmacy registrations with the Board. In addition, she reported that while some facilities at one time maintained a nonresident pharmacy registration with the Board, these facilities currently only maintain an out-of-state wholesaler registration with the Board. Ms. Anderson further reported that some of the dual-licensed facilities and out-of-state wholesaler facilities that were at one time nonresident pharmacies are believed to be registered manufacturers with the Federal Food and Drug Administration (FDA). However, it is unknown whether they have had drugs approved by the FDA to be moved into interstate commerce by the submission and approval of either a New Drug Application or Abbreviated New Drug Application. After careful consideration of the available information, the Board voted unanimously to send explanatory letters and affidavits to each of these out-of-state prescription drug wholesalers to attest that each facility will only distribute drugs into Colorado that have been approved by the FDA to be moved into interstate commerce. The Board also directed its staff to include information in both the explanatory letters and affidavits that address a requirement to register with the FDA as repackagers if these entities intend to distribute repackaged drugs into Colorado.

The Board considered correspondence from the American Academy of Ophthalmology regarding the use of compounded and repackaged drugs for office use. After careful consideration of the available information, the Board voted unanimously to send correspondence back to the American Academy of Ophthalmology stating the following: (1) While Colorado law allows its in-state pharmacies, within limitations, to compound and distribute medications to practitioners for use in their offices, nonresident pharmacies may only dispense and deliver prescriptions into Colorado pursuant to a patient-specific order; (2) the repackaging of bevacizumab is not compounding (it is repackaging) and as such, pharmacies that wish to repackage bevacizumab must be registered with the FDA as repackagers and be registered with the Board as wholesalers to distribute this product; (3) the Board has adopted rules that incorporate much of United States Pharmacopeia Chapters 795 and 797; and (4) when appropriate, the Board does engage national and state provider associations when conducting rulemaking.

The Board considered correspondence from DCI Pharmacy Services, a Board registered nonresident pharmacy, regarding its assertion that it may distribute prescription drugs to entities in Colorado which are under common ownership with DCI Pharmacy Services. After careful consideration of the available information, the Board voted unanimously to send correspondence back to DCI Pharmacy Services stating that it may only dispense and deliver prescriptions into Colorado pursuant to patient-specific orders. If the pharmacy wishes to distribute drugs it manufactures into Colorado, it would need a manufacturer registration with the FDA, an out-of-state prescription drug wholesaler from the Board, and it would need to receive approvals for a New Drug Application or an Abbreviated New Drug Application for any drug it wishes to distribute into Colorado.

The Board reviewed proposed rule language for sterile product packaging. After careful consideration of the available information, the Board voted unanimously to move the proposed language to a future rules hearing as amended.

The Board reviewed proposed rule language for prescription flavoring. After careful consideration of the available information, the Board voted unanimously to move the proposed language to a future rules hearing.

Ms. Anderson discussed with the Board highlights of her participation in a December 2012 intergovernmental meeting she attended between board of pharmacy directors and the FDA in Silverspring, MD. The Board noted the information.

Ms. Anderson presented copies of reports detailing recent Board inspections of Colorado-based pharmacies that engage in compounding. The Board noted the information.

The Board directed Board staff to invite a representative from the FDA to a future meeting to learn more about its registration process for manufacturing and repackaging.

The Board directed Board staff to initiate a task force to revisit the practice of compounding. Ms. Anderson stated that she will provide a report from the last compounding task force from 2006 for the Board's March 21, 2013 meeting.

The Board considered a correspondence from the Colorado Retina Associates and the Retina Consultants of Southern Colorado, P.C. regarding obtaining bevacizumab for office use. After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

After Executive Session, the Board voted unanimously to send correspondence back to the Colorado Retina Associates and the Retina Associates of Southern Colorado, P.C. offering the following suggestions for obtaining bevacizumab for administration to patients: (1) provide a patient-specific prescription order for the drug to a pharmacy; (2) draw the needed amount of the drug from the manufacturer's vial for immediate administration; (3) obtain the repackaged drug from an FDA registered repackager who is registered with the Board as a wholesaler or (4) in the case of bevacizumab, use the more expensive product, ranibizumab, which is approved by the FDA for age related macular degeneration.

The Board also welcomed a presentation from physicians from the Retina Consultants of Southern Colorado at an upcoming meeting.

Substance Abuse Stipulation Requirements

The Board reviewed recommendations regarding substance abuse stipulation requirements from Peer Assistance Services, Inc. (PAS). In addition, it reviewed information from other states and substance abuse stipulatons.

After careful consideration of the available information, the Board voted unanimously to make the following changes: (1) reduce the minimum work requirement for substance abuse stipulations from 80 hours per month throughout the duration of the stipulation to 60 hours per month for a majority of the time a licensee is serving a substance abuse stipulation; (2) to allow PAS to approve whether or not a licensee serving a substance abuse stipulation can serve as a pharmacist manager or consultant pharmacist of a Board-registered outlet; and (3) for the Board to consider, on a case-by-case basis, all requests for stipulation modifications from prior substance abuse stipulations and all requests to practice pharmacy in another state while serving a substance abuse stipulation.

Profession of Pharmacy

The Board reviewed rules from other states that address issues partaing to working conditions in pharmacies. After careful consideration of the available information, the Board tabled further consideration of this matter pending receipt of a legal opinion.

Drug Therapy Management

The Board compared its Rule 6.00.00 for potential conflicts with Medical Board Rule 900 with regard to how drug therapy management is addressed. After careful consideration of the available information, the Board determined that no conflicts exist.

EXECUTIVE SESSION

At 12:12 p.m., Board President Paul Limberis, R.Ph. moved that the Board enter into Executive Session.

The motion was seconded. The vote was unanimous with six votes approving the motion to go into Executive Session and none opposing.

The Board exited Executive Session at 12:45 p.m.

ADJOURNMENT

The Board adjourned at 12:52 p.m.

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Paul Limberis, R.Ph. Approval Date
Board President